

## **Conservative interventions for urinary incontinence in women: an overview of Cochrane systematic reviews**

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## **Conservative interventions for urinary incontinence in women: an Overview of Cochrane systematic reviews (Protocol)**

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# Conservative interventions for urinary incontinence in women: an Overview of Cochrane systematic reviews

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## ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To synthesise Cochrane reviews of conservative interventions, as described above, for the prevention or treatment of female urinary incontinence. Outcomes are described below.

## BACKGROUND

At least one-quarter of all adult women have urinary incontinence (UI), with prevalence increasing with age ([Sandvik 2000](#)). Around 20% of women with urinary problems seek professional help; this percentage increases with advancing age and is higher among women with other concomitant urogenital problems ([Morrill 2007](#)).

Evidence suggests that for the majority of women affected, UI impacts significantly on daily living. It has been shown to interfere with physical, psychological and social activities of women, reducing general health, wellbeing and quality of life ([NICE 2013](#)). It is associated with an increased prevalence of major depression ([Melville 2009](#)); and in older women is linked to social isolation and psychological distress ([Bogner 2002](#)). UI can cause a number of serious medical conditions, such as perineal rash, pressure ulcers and urinary tract infections and increases the risk of admission to long-term residential care ([Hunnskaar 2002](#)). The annual cost to

the NHS of treating clinically significant female UI has been estimated to be GBP 233 million ([Perry 2000](#)). This does not include the personal costs borne by the women affected, which have been estimated to be GBP 178 million ([Turner 2004](#)). UI is therefore prevalent and costly to healthcare providers; and to women both financially and in terms of physical and mental wellbeing.

Urinary incontinence can result from damage to the neural control of the bladder or the pelvic floor muscles, or from direct mechanical trauma to the pelvic floor ([Glazener 2001](#)). The risk is increased by vaginal (particularly assisted) delivery, increasing age and parity, obesity and the menopause ([MacArthur 1993](#); [Wilson 1996](#); [Thom 1997](#)). UI may also be caused by trauma or disease to the bladder.

Incidence figures depend on the definition used and the population investigated, with reported annual incidence rates (numbers of new cases) of urinary incontinence ranging from 1% to 11%, and the annual remission rate from 6% to 11% ([Hunnskaar 2005](#)).

## Description of the condition

Urinary incontinence (UI) is the involuntary loss of urine, and can be caused by a number of different conditions (Blaivas 1997; Haylen 2010).

Continence is achieved through an interplay of the normal anatomical and physiological properties of the bladder, urethra, sphincter and pelvic floor; and the nervous system co-ordinating these organs. The active relaxation of the bladder coupled by the ability of the urethra and sphincter to contain urine within the bladder by acting as a closure mechanism during filling, allow storage of urine until an appropriate time and place to void is reached. The role of the pelvic floor in providing support to the bladder and urethra, and allowing normal abdominal pressure transmission to the proximal urethra is also considered essential in the maintenance of continence. Crucial to the healthy functioning of the bladder, urethra, sphincter and pelvic floor is coordination between them, facilitated by an intact nervous system control. Incontinence occurs when this normal relationship between the lower urinary tract components is disrupted, resulting from nerve damage or direct mechanical trauma to the pelvic organs. Advancing age, higher parity, vaginal delivery, obesity and menopause are associated with an increase in risk (Rehman 2011).

There are three main types of UI:

1. **Stress urinary incontinence (SUI):** is the complaint of involuntary loss of urine on effort or physical exertion (e.g. sporting activities) (Haylen 2010). Stress UI is a symptom, rather than a condition. Research has shown that about 50% of the women below the age of 65 years with UI had stress UI (Milsom 2012).

2. **Urgency urinary incontinence (UUI):** is the complaint of involuntary loss of urine associated with urgency (Haylen 2010). Isolated UUI is the least common type, accounting for 10% of women who have UI (Milsom 2012).

3. **Mixed urinary incontinence (MUI):** is the complaint of

involuntary loss of urine associated with urgency and also with effort or physical exertion or on sneezing or coughing (Haylen 2010). It occurs in around 30% of women (Milsom 2012).

In addition, loss of urine may occur:

- At night (nocturnal enuresis, the complaint of loss of urine occurring during sleep) or the interruption of sleep because of the need to urinate, with loss of urine if the toilet is not reached in time to void); and

- During intercourse (coital incontinence, the complaint of involuntary loss of urine with coitus, occurring with penetration or intromission, or at orgasm)

## Description of the interventions

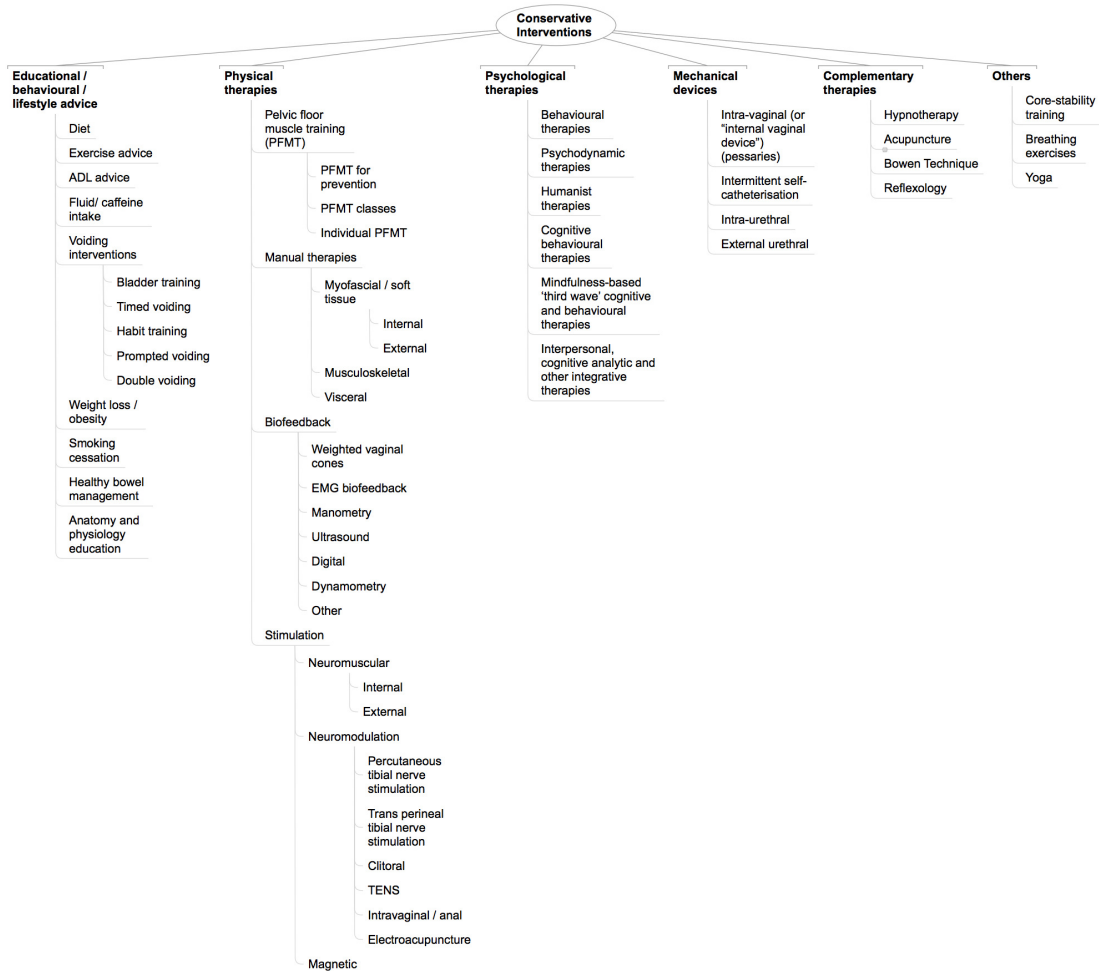
A wide range of interventions can be delivered in an attempt to reduce the symptoms of UI in women, including conservative, pharmacological and surgical interventions. Conservative interventions are generally recommended as the first line of treatment for women with UI (NICE 2013), and are therefore the focus of this overview. However we will include reviews in which the comparator intervention is a pharmacological, surgical or other management intervention. We will include reviews in which a single conservative intervention is delivered or in which two or more conservative interventions are delivered in combination.

The type of intervention selected for an individual woman will depend on an assessment of their symptoms, types of incontinence, factors contributing to UI, associated medical conditions, and clinician and individual choice.

## Conservative interventions

Conservative management of UI largely comprises physical, behavioural and psychological interventions, often delivered in combination (French 2010), including (but not limited to) (see Figure 1):

Figure 1.



- **Mechanical devices** to prevent or reduce urinary leakage. These include pessaries (urethral and vaginal inserts) and mechanical plugs/patches (Lipp 2014).

- **Physical therapies** - for women with SUI the aim is to improve muscle control. This principally includes pelvic floor muscle training, which can be delivered with or without the use of assistive devices such as weighted vaginal cones, biofeedback or electrostimulation (Dumoulin 2014).

- **Educational, behavioural and lifestyle advice** to enhance management of urinary incontinence. These commonly include methods of toileting assistance, such as prompted voiding, habit/ bladder retraining and timed voiding (Eustice 2000; Ostaszkievicz 2004a; Ostaszkievicz 2004b), and advice about lifestyle factors, such as weight loss, management of fluid intake, caffeine and alcohol intake and physical activity and exertion (Imamura 2015).

- **Psychological interventions.** A range of psychological therapies, based on a number of different philosophical or theoretical approaches, can be used to help a woman cope with her UI symptoms and improve her quality of life. These include the Health Belief Model (Chiarelli 1999); Theory of Planned Behaviour (Whitford 2011); and the Social Cognitive theory (Self-efficacy) (Alewijanse 2003a; Alewijanse 2003b).

- **Complementary therapies.** The Complementary Medicine Field of the Cochrane Collaboration defines complementary medicine as “practices and ideas which are outside the domain of conventional medicine in several countries” and which are defined by its users as “preventing or treating illness, or promoting health and wellbeing” (Smith 2006). Therapies which are considered complementary practices in one country or culture may be considered conventional in another. For the

purpose of this overview, we define complementary *therapies* as complementary *interventions*, such as acupuncture/electroacupuncture, reflexology, but excluding medicines or consumed remedies (i.e. excluding herbal medicines, traditional Chinese medicines, homeopathic remedies) (Bo 2013).

In addition to these groups of interventions, there are a growing number of digital health interventions which use new technologies and media to support and enhance the delivery of conservative management of UI. In particular, digital health interventions can help support the delivery of behavioural-based interventions, and may be used as part of bladder training or voiding programmes, or both; (see [How the interventions might work](#) for further description of types of conservative interventions within these categories). These conservative interventions are the focus of the Overview, and the following interventions will only be included if they are used as comparators in the included evidence.

### Pharmacological (drug) interventions

A number of different pharmacological therapies have been investigated for the treatment of urinary incontinence, including

- oestrogen (Cody 2012)
- anticholinergic drugs (Rai 2012)
- adrenergic agents (Alhasso 2005) and
- botulinum toxin (Duthie 2011).

These interventions may have local or systemic effects.

### Surgical interventions

Surgical procedures to remedy urinary incontinence generally aim to lift and support the urethrovesical junction. It has been identified that there is disagreement about the precise mechanisms achieved by surgery and that the choice of procedures is often influenced by a number of different factors, including co-existent problems, a surgeon's specialty and preference, and the physical features of the person affected (Glazener 2001). Surgical methods principally include

- open abdominal retropubic suspension (Lapitan 2016)
- laparoscopic retropubic suspension (Dean 2006)
- midurethral sling procedures (Ford 2015)
- traditional suburethral sling procedures (Rehman 2011)
- anterior vaginal repair (Glazener 2001)
- bladder neck needle suspensions (Glazener 2014)
- peri-urethral injections (Kirchin 2012)
- artificial sphincters (Islah 2013)

### Other interventions for UI

In addition to these three groups of interventions, specialised products can be used in the management or treatment of UI. These include special pads and bedsheets, as well as catheters, sheaths and bags.

### Investigation of UI

There are a number of different techniques for the diagnosis of the cause of urinary incontinence, including urodynamic investigations (Clement 2013), diaries, pad tests (Groutz 2000), and imaging techniques such as x-rays and ultrasound.

### How the intervention might work

Conservative interventions can work in a variety of ways, and the mechanism of action may be mechanical, physical, behavioural or psychological, or a combination of these. For categories of conservative interventions, see [Figure 1](#).

### Mechanical devices

These are physical devices that are designed to stop or control urinary leakage. They can be inserted inside the vagina or urethra (internal placement) or applied to the external surface of the urethra (external placement) (Lipp 2014). These devices work in a number of different mechanical ways:

- **Intravaginal (or 'internal vaginal device') (also known as pessaries):** These devices are inserted into the vagina with the aim of supporting the bladder neck to improve stress urinary incontinence (SUI). Some devices are also shaped with a knob which compresses the urethra, which also helps to reduce SUI.
- **Intra-urethral:** This is a device that is inserted into the urethra acting like a plug to prevent leakage. It is inserted and removed by the individual as required.
- **External urethral:** This is a device that is applied like a seal to the outer surface of the urethral opening (external placement) to stop leakage of urine from the urethra.

### Physical therapies

Physical therapies are provided by rehabilitation professionals, using specially designed exercises, delivered with or without the use of assistive devices, to help individuals regain or improve physical control of their bladder. These

- **Pelvic floor muscle training** involves repetitive selective voluntary contraction and relaxation of specific pelvic floor muscles. PFMT exercises can be taught to women by rehabilitation professionals, but then are carried out independently by the woman on a regular basis, with or without supervision. PFMT can improve the strength, endurance and coordination of these muscles (Alves 2015; Dumoulin 2014). For those with UUI the biological rationale is based on Godec's observation that a detrusor muscle contraction can be inhibited by a pelvic floor muscle contraction induced by electrical stimulations (Godec 1975). Further de Groat 1997 demonstrated that during urine storage there is an increased pudendal nerve outflow response to the external urethral sphincter increasing intraurethral pressure and representing what he termed a "guarding reflex" for incontinence (de Groat 1997;

de Groat 2001). Additionally, Morrison 1995 demonstrated that Barrington's micturition centre excitatory loop switches on when bladder pressures are between 5 to 25 mmHg, while the inhibitory loop is predominantly active above 25 mmHg. Inhibition involves an automatic (unconscious) increase in tone for both the pelvic floor muscle and the urethral striated muscle. Thus, voluntary pelvic floor muscle contractions may be used to control UUI. After inhibiting the urgency to void and the detrusor contraction, the woman can reach the toilet in time to avoid urine leakage.

- **Biofeedback** is a technique used to supplement or enhance PFMT. Information about a normally unconscious physiological process is presented to the individual and the therapist as a visual, auditory or tactile signal (Sandweiss 1985). Such feedback enables a person to identify and modify a bodily function of which they may be unaware. Typically this may involve digital palpation or the use of a device to record the biological signals (e.g. squeeze pressure, electrical activity, pelvic floor morphometry using ultrasound) during a voluntary pelvic floor muscle contraction and presentation of this information back to the woman in auditory or visual form. Examples of this feedback are verbal encouragement, a louder sound with a stronger squeeze or an increasing number of lights on a visual display as the strength of the squeeze increases, and visual display of levator ani contraction on an ultrasound screen. Thus for a muscle that cannot be seen, unlike for example the quadriceps muscles of the knee, the woman receives some sort of signal about their ability to use their pelvic floor muscle. Biofeedback may also be provided by the use of weighted vaginal cones, which are small weights placed in the vagina which require contraction of the pelvic floor muscle to prevent them from slipping out. The cones provide a form of biofeedback as the sensation of one slipping out induces a pelvic floor muscle contraction which may both strengthen muscles and help to synchronize muscle contraction with increases in abdominal pressure (Herbison 2013)

- **Stimulation** A number of different types of stimulation, including electrical and magnetic stimulation, can be delivered through either surface electrodes (transcutaneous) or via direct stimulation (percutaneous) with the aim of stimulating the nerve supply and altering nerve activity. Stimulation of nerve supply is thought to improve muscle tone and sensation of the pelvic floor muscles, enhancing muscle control; and it also aims to reduce detrusor contraction in the case of UUI. Electrical stimulation therapy can be used to treat overactive bladder via different routes, such as implantable or internal electrodes (sacral neuromodulation) and non-implantable or external electrodes. The latter can be sub-classified as endocavitary electrodes (rectal or intravaginal) or percutaneous electrodes (tibial nerve stimulation). Cadwell 1963 was the first to report the use of intravaginal electrical stimulation (IES) in the treatment of urinary incontinence. Subsequently, Messelink 1999 also used it

with satisfactory results. IES using frequencies below 12 Hz stimulates the pudendal nerve, which may inhibit the detrusor muscle, reduce involuntary contractions and, consequently, reduce the number of micturitions in 24 hours (Messelink 1999). Electrical stimulation also works in a passive way, helping women to become conscious of the perineal muscle contraction and this may, in turn, help to inhibit detrusor involuntary contractions (Amaro 2003). IES can be used on its own or in association with pelvic floor muscle exercises, often indicated in SUI and OAB. Percutaneous tibial nerve stimulation (PTNS) is a form of neuromodulation that delivers retrograde stimulation to the sacral nerve plexus through percutaneous electrical stimulation of the posterior tibial nerve via a needle electrode inserted cephalad to the medial malleolus, an anatomical area recognized as the bladder centre (Hajebrahimi 2015).

- **Magnetic stimulation** appears to induce inhibitory effects on detrusor overactivity in a similar manner to electrical stimulation, with the significant clinical advantage of being non-invasive (Takahashi 2003).

- **Bladder training** encourages people to extend the time between voiding so that continence might be regained. This can take months to achieve but may help people who are physically and mentally able to use this method. For those with UUI the biological rationale is based on Godec's observation that a detrusor muscle contraction can be inhibited by a pelvic floor muscle contraction induced by electrical stimulation (Godec 1975). Further de Groat 1997 demonstrated that during urine storage there is an increased pudendal nerve outflow response to the external urethral sphincter increasing intraurethral pressure and representing what he termed a "guarding reflex" for incontinence (de Groat 1997; de Groat 2001). Additionally, Morrison 1995 demonstrated that Barrington's micturition centre excitatory loop switches on when bladder pressures are between 5 to 25 mmHg, while the inhibitory loop is predominantly active above 25 mmHg. Inhibition involves an automatic (unconscious) increase in tone for both the pelvic floor muscle and the urethral striated muscle. Thus, voluntary pelvic floor muscle contractions may be used to control UUI. After inhibiting the urgency to void and the detrusor contraction, the woman can reach the toilet in time to avoid urine leakage (Wallace 2004)

- **Manual therapy** is defined as a clinical physical approach utilizing specific hands-on techniques. It may include massage, soft tissue mobilization, various connective tissue techniques, myofascial release, mobilization of joints, joint manipulation or mobilization of nerve tissue. It is used to diagnose and treat soft tissues and joint structures for the purpose of modulating pain; increasing range of motion; reducing soft tissue oedema; inducing relaxation; improving contractile and non-contractile tissue extensibility, and/or stability; facilitating movement; and improving function (Personal Communication: Bø 2016).



In addition to these groups of interventions, there are a growing number of **digital health interventions** which use new technologies and media to support and enhance the delivery of conservative management of UI. In particular, digital health interventions can help support the delivery of behavioural-based interventions, and may be used as part of bladder training or voiding programmes.

## Educational, behavioural and lifestyle advice

Several lifestyle factors are thought to play a role either in the onset or later in the resolution or management of UI. These include:

- **Diet:** many dietary factors are thought to aggravate urinary urgency, and may also relate to weight gain or constipation, or both (see below). Dietary advice can therefore be beneficial to the management of UI (Imamura 2015).

- **Exercise and activities of daily living (ADL) advice:** weakened pelvic floor support structures and raised intra-abdominal pressure caused by heavy lifting and strenuous activity may result in UI. Strenuous activity alone may also increase incontinence in the short term. Appropriate advice can help women to manage the impact of exercise and daily physical activity on UI, whilst maintaining a healthy lifestyle (Bo 2013).

- **Fluid/caffeine intake:** worsening of urinary urgency, frequency and incontinence is often reported after consuming caffeine, alcohol, fizzy drinks, sweetened diet drinks or excessive fluids. Caffeine can increase bladder muscle contractility, whereas alcohol or excessive fluids may have a diuretic effect (Imamura 2015).

- **Voiding interventions:** this is a broad term which is used to describe any type of scheduled toileting intervention, which can include programmes of scheduled bladder voiding and bladder training (aimed at trying to correct faulty habit patterns of frequent urination (if present), improve control over bladder urgency, prolong voiding intervals, increase bladder capacity, reduce incontinent episodes, and restore women's confidence in controlling bladder function) (Eustice 2000).

- **Weight loss/obesity:** obesity and urinary incontinence are common problems in women. Obese women have higher intra-abdominal pressure than non-obese women, and it is thought that this chronically elevated pressure may predispose to incontinence in two ways: firstly by weakening pelvic floor support structures; and secondly by raising the intra-abdominal pressure (Imamura 2015).

- **Smoking cessation:** there is evidence of a relationship between cigarette smoking and UI, although the mechanism is not fully understood (Bump 1992). Chronic coughing among smokers may also contribute to UI by raising intra-abdominal pressure (Imamura 2015).

- **Healthy bowel management:** constipation can obstruct the bladder, preventing adequate voiding and resulting in urine leakage. Chronic straining may also be a risk factor in the development of UI. Advice which avoids or limits constipation or

chronic straining may improve or prevent UI (Imamura 2015).

- **Anatomy and physiology education:** educational interventions to teach women about the causes of their UI may improve understanding of the condition and may therefore help women manage their symptoms (Imamura 2015).

## Psychological therapies

There are many different types of psychological therapies, which are based on a range of theoretical and philosophical standpoints. These are often forms of talking therapy, with individuals or in groups, but may also include interventions such as telephone or internet-based support. Psychological therapies are generally aimed at helping people change the way they think and behave. Psychological therapies may help women with UI to manage and maintain a sense of wellbeing and enhance quality of life. For the purposes of this overview we will consider psychological therapies within the categories proposed and described by Shinohara 2013, as follows:

- **Behavioural therapies:** this includes behavioural therapy, behavioural activation, social skills training/assertiveness training, and relaxation therapy.

- **Cognitive-behavioural therapies:** this includes cognitive therapy, rational emotive behavioural therapy, problem-solving therapy, self-control therapy, and courses aimed at coping with depression.

- **Mindfulness-based 'third wave' cognitive and behavioural therapies:** this includes acceptance and commitment therapy, compassionate mind training, functional analytical psychotherapy, extended behavioural activation, meta-cognitive therapy, mindfulness-based cognitive therapy, and dialectical behavioural therapy.

- **Psychodynamic therapies:** this includes interventions based on Drive/structural model, Relational model, and Integrative analytical model.

- **Humanist therapies:** this includes Person-centred therapy, Gestalt therapy, experiential therapies, transactional analysis, existential therapy, and non-directive/supportive therapies.

- **Interpersonal, cognitive analytic and other integrative therapies:** this includes interpersonal therapy, cognitive-analytic therapy, psychodynamic-interpersonal therapy, cognitive-behavioural analysis system of psychotherapy, counselling, and motivational interviewing.

## Complementary therapies

A number of different alternative therapies, such as hypnotherapy and acupuncture, may be used, often alongside other conservative interventions. These interventions are generally provided to help people feel better and to promote health and wellbeing. Complementary therapies used to reduce symptoms and promote wellbeing in women with UI may include (but are not limited to):

- **Acupuncture/Electroacupuncture:** this is the practice of inserting a needle or needles into certain points in the body for therapeutic purposes (Wang 2013).
- **Hypnotherapy:** this is a form of psychotherapy that can be used to create subconscious change in an individual in the form of new responses, thoughts, attitudes, behaviours or feelings (Komesu 2011).
- **Bowen Technique:** this is a hands-on therapy in which very gentle pressure is applied to specific points on the body (Wilks 2007).
- **Reflexology:** is a massage used to relieve tension and treat illness, based on the theory that there are reflex points on the feet, hands, and head linked to every part of the body (Yau 2006).

### Other conservative interventions

There are a number of other conservative interventions which may be used for women with UI, which do not fit within the above categories. These can include (but are not limited to):

- **Core-stability training:** specific exercises, comprising stretching and strengthening exercises which are adapted to the condition of the intervention, aimed at improving muscle strength and control around the pelvic area. These exercises may be delivered by an exercise instructor or person who is not a rehabilitation professional. Increased muscle strength and control around the pelvic area may improve the symptoms of UI by changing intra-abdominal pressure and increasing pelvic floor muscle control (Bø 2013).
- **Breathing exercises/Hypopressive exercise:** breathing exercises generally aim to complement PFMT by changing the pressure on the abdominal wall and improving the overall quality of pelvic floor muscle training exercises (Bø 2013).
- **Pilates:** modern Pilates exercise programmes incorporate exercises that involve breathing and contraction of pelvic floor muscles. The pelvic floor muscles are not specifically trained, but pelvic floor muscles are trained incidentally during exercise and movement. The co-contraction of pelvic floor muscles that occurs incidentally during Pilates exercises will counteract increases in intra-abdominal pressure that occur during exercise, preventing leakage and strengthening pelvic floor muscles (Bø 2013).
- **Yoga:** a physical, mental and spiritual practice, which may benefit UI through changes to physical (e.g. muscle stretching, control) and psychological mechanisms (Bø 2013).
- **Paula Method:** all sphincters in the body work simultaneously so exercising the ring muscles of the mouth, eyes, or nose may result in co-contraction and strengthening of the pelvic floor muscles (Bø 2013).
- **Tai Chi:** Tai Chi is an ancient exercise regimen originating in China and has widespread use as exercise for general health in China. Chang 1986 describes an exercise called
  - 'the deer' involving contraction of the anal sphincter. The

exercise is recommended for both men and women for conditions related to the pelvic area (Bø 2013).

- **Posture:** Theory: Carriere 2006 has claimed that "poor posture" can lead to pain and dysfunction in the pelvic floor. It is thought that optimal strategies for transferring loads will balance control of movement while maintaining optimal joint axes, maintain sufficient intra-abdominal pressure without compromising the organs (preserve continence, prevent prolapse or herniation) and support respiration. Non-optimal strategies for posture, movement and breathing, or combinations thereof, create failed load transfer which can lead to pain, incontinence and breathing disorders (Bø 2013).

### Why it is important to do this overview

Conservative management is recommended as a first line of treatment for women with UI (NICE 2013). They often have complex aetiologies and co-morbid conditions and identifying the most effective rehabilitation interventions is not always easy. Given the importance of curing, improving or managing UI symptoms to allow women to have an active lifestyle and good quality of life, there are a substantive and growing number of randomised controlled trials (RCTs) and systematic reviews relating to the effectiveness of conservative interventions for UI. Despite this growing body of evidence, current clinical practice often does not reflect the available increasing evidence-base. This important area of practice receives little attention in undergraduate physiotherapy education, for example, less than 2 hours in the UK (McClurg 2013), and is largely driven by post-graduate courses and peer support in Canada (Francis 2012). Lack of sufficient time to identify and synthesise evidence is cited as the key barrier to evidence-utilisation within UI rehabilitation (McClurg 2013).

It has been recognised that a large and growing body of systematic reviews can be overwhelming for decision makers, and health-care practitioners do not have time to keep up to date with this evidence-base (Bastian 2010). The Cochrane Incontinence Group has (in December 2015) 107 reviews and protocols relating to urinary incontinence, of which 55 are related to mechanical, physical, psychological or educational interventions for the treatment or prevention of urinary incontinence (CIG 2015). This large number of Cochrane reviews may be overwhelming for healthcare practitioners seeking best evidence relating to conservative interventions for urinary incontinence, and create a barrier to evidence-based practice. It is therefore important to bring all Cochrane reviews relating to conservative interventions for the prevention or treatment of female urinary incontinence together, in order to signpost clinical decision makers to best evidence and support efficient use of best evidence.

Furthermore, while Cochrane reviews synthesise available RCT evidence relating to UI in women, these Cochrane reviews often explore the effects of specific single interventions compared to placebo or control interventions. However, in clinical practice, the

choice will be generally be between a variety of interventions (or a combination) rather than an all-or-nothing choice of using or not using one of the interventions. Thus the synthesis of evidence relating to single, specific UI interventions fails to facilitate translation of evidence into clinical practice or decision making.

A Cochrane overview of conservative interventions for women with UI will synthesise into one accessible, comprehensive document all high quality evidence about UI conservative interventions, assess the limitations of current best evidence and enable indirect comparisons of the effects of different interventions on UI. This proposed overview will support evidence-based management of UI amongst key decision makers (such as clinicians, policy makers, or informed health service users) and educators of Allied Health Professionals.

## OBJECTIVES

To synthesise Cochrane reviews of conservative interventions, as described above, for the prevention or treatment of female urinary incontinence. Outcomes are described below.

## METHODS

### Criteria for considering reviews for inclusion

We will include any Cochrane review that meets the following criteria:

**Participants:** Reviews of studies in which the participants are female adults ( $\geq 18$  years) with a clinical diagnosis of UI, regardless of cause or comorbidities, and including stress, urge or mixed UI.

**Interventions:** Reviews of studies which investigate a conservative intervention for which the primary aim is to prevent, improve or cure UI. Conservative interventions include those listed in [How the interventions might work](#), and are illustrated in [Figure 1](#).

As long as the above inclusion criteria are met, we will include reviews of trials in which the participants:

- have other, co-morbid, health-related problems including (but not limited to): pregnancy and delivery, cancer, neurological diseases, chronic respiratory disease, learning difficulties and dementia.
- can be recruited from any setting, including community, hospital or care home environments.

We will consider reviews which include both male and female participants, but will only include reviews in which we can extract data relating specifically to the female participants.

We will exclude reviews of surgical or pharmacological interventions, products to manage leakage of urine and investigative techniques, unless these are compared with a conservative interven-

tion. We will include reviews in which a conservative intervention is considered to be a control intervention.

### Search methods for identification of reviews

Relevant reviews will be identified from the Cochrane Incontinence Review Group's list of published Cochrane reviews. We will also search the Cochrane Database of Systematic Reviews (part of *The Cochrane Library*) using the strategy given in [Appendix 1](#). Titles and protocols registered with the Cochrane Incontinence Review Group will also be considered.

### Data collection and analysis

During the process of data collection and analysis, evidence relating to stress, urgency or mixed UI will be separated, and will be subgrouped according to these three separate groups.

The aim of this stage of the overview is on systematically bringing together assessment of methodological quality and presentation of data from the included reviews. With the exception of the final section, 'Data analysis', description of methods within subsequent sections will therefore refer to *synthesis* of data as presented within the included reviews, and *not* to any re-analysis or pooling of data.

### Selection of reviews

Two independent reviewers will consider titles and abstracts from the identified reviews and apply the inclusion criteria (see [Criteria for considering reviews for inclusion](#)). If there is disagreement between reviewers, they will reach consensus through consideration and discussion of the full paper, involving a third reviewer if necessary.

We will contact authors of any titles or protocols which appear to meet our selection criteria, identifying those which authors indicate should be completed within 3 months of our initial search date. We will also contact authors of all completed reviews meeting our selection criteria for which the search date is more than 12 months ago, asking if an update is anticipated within this 3-month period. Initial contact with review authors will be made via the Cochrane Incontinence Review Group. When authors indicate that a review should be finished/updated within this timeframe, we will send reminder emails in advance of this date to check on progress, and to gain access to relevant pre-publication data where possible.

### Data extraction and management

Two overview authors will extract data independently. Disagreements will be resolved by discussion, with assistance from a third overview author if necessary. We will use a data collection form specifically designed and piloted by the overview author team.

Onto this form, we will extract and record key features of each review including details of the aims and rationale, types of studies, participants, interventions, comparisons, outcomes assessed, date of last search and meta-analyses completed.

We will systematically synthesise, using a spreadsheet, the studies included within all identified reviews to explore whether any reviews covered the same studies. When overlap between reviews is identified, two overview authors will discuss the overlap with consideration of each review question and comparisons explored, the date of the last search and key aspects of methodological quality (e.g. types of studies included, risk of bias assessment). We will use these details to reach agreement regarding which data from which review comparisons should be included within the overview.

### Type of UI

During this phase of data extraction two independent reviewers will note whether each included review includes evidence relating to stress, urgency or mixed UI, or a combination thereof. We will resolve any disagreements through discussion, using a third reviewer if necessary. We will compile a list of which reviews relate to each of these three types of UI. All subsequent stages of the overview will be completed in triplicate, for:

- Conservative interventions for management of stress UI
- Conservative interventions for management of urgency UI
- Conservative interventions for management of mixed UI

We anticipate that some reviews may include populations with more than one type of UI. If separate data are available for populations with different types of UI then we will include the relevant data within the synthesis relating to stress/urgency/mixed UI. Thus one review may be included in more than one of the above groups. If a review only contains data relating to a combined population, and separate data are not available, then we will include this review within a fourth section:

- Conservative interventions for management of stress, urgency or mixed UI (combined populations)
- Unclear as some reviews do not define populations

### Criteria for identifying relevant comparisons

We will use extracted data to determine which reviews have meta-analyses (comparisons) of relevance to this overview according to the three populations of women with UI (SUI, UUI, MUI). Relevant comparisons will evaluate the effect on the stated primary or secondary outcomes of interest to the overview by comparing the effects of:

1. Any conservative intervention versus control, placebo or standard care
2. Any conservative intervention versus other active intervention (i.e. surgical or pharmacological intervention)
3. One conservative intervention versus another conservative intervention

4. Comparisons of different doses, intensities or timing of delivery of conservative intervention

### Primary Outcomes

The primary outcomes of interest to this overview are:

1. Condition-specific quality of life, as measured by specific instruments designed to assess the impact of UI symptoms on the life of a woman, such as King's Health Questionnaire (Kelleher 1997), Incontinence Quality of Life (I-QOL) (Wagner 1996) and Bristol Female Lower Urinary Tract Symptoms (B-FLUTS) questionnaire (Jackson 1996)
2. Symptomatic cure or improvement of UI, as reported by the woman (including through self-report or bladder diaries)

### Secondary Outcomes

1. Participant-reported cure only, accepting the definition of cure used in the review. .
2. General quality-of-life measures (i.e. not condition-specific), such as Short Form-36
3. Adverse effects (e.g. discomfort, soreness, pain, bleeding)
4. Measures of anxiety/depression, such as Hospital Anxiety and Depression Scale (HADS)
5. Other clinician-measured or observed outcomes (e.g. pad tests, pad weights, frequency of UI). (Note: even if reported as 'cure/improvement', clinician-based measures will be considered secondary outcomes)
6. Other participant self-report not presented as cure or improvement
7. Pelvic floor muscle strength/function (e.g. digital evaluation, pelvic floor muscle dynamometry or electromyography, vaginal squeeze pressure, perineal ultrasound)
8. Skin integrity
9. Adherence to intervention (including measures of usability/acceptability)
10. Urodynamics (urodynamic testing) (e.g. post-void residual volume, rate of bladder emptying, detrusor pressure)
11. Socioeconomic measures (e.g. cost of intervention, economic analysis, resource implications)
12. Other

We will consider outcomes at three time periods:

1. The end of treatment
2. Up to one year after end of treatment
3. More than one year after end of treatment.

We will categorise outcomes pooled within meta-analyses as either 'immediate' (i.e. at the end of intervention) or 'follow-up', documenting and reporting within tables the timepoint of the data pooled, as reported in the included review.

We will identify information relating to all outcomes synthesised within the included reviews, but will only extract data relating to effect size from relevant meta-analyses of comparisons relating to these stated outcomes of interest.

### Data extraction for relevant comparisons

Data extracted relating to meta-analyses will include:

1. The number of trials and participants
2. The mean difference or standardised mean difference (for continuous data)
3. The risk ratio or risk difference (for binary data), with 95% confidence intervals
4. The  $I^2$  statistic for heterogeneity

Where meta-analyses include presentation of subgroup data these will also be documented. These data will be checked by a second overview author with reference to the published review.

### Assessment of methodological quality of included reviews

For each relevant comparison reported in each included review, one overview author will systematically extract data on the risk of bias (as documented in the published review; ideally using the Cochrane 'Risk of bias' tool, Higgins 2011b) relating to trials within each comparison and the results of the meta-analyses performed.

### Quality of included reviews

Two independent overview authors will assess the methodological quality of the included reviews using the ROBIS (Risk Of Bias In Systematic reviews) tool (Whiting 2015). ROBIS is completed in three phases: (1) Assess relevance; (2) identify concerns with the review process; and (3) judge risk of bias in the review. The second phase will include assessment of whether

- review eligibility criteria were clear, appropriate and pre-specified;
- all relevant primary studies should have been identified and included in the review;
- bias may have been introduced through the data collection or risk of bias assessment processes;
- appropriate methods have been used for any meta-analyses.

All signalling questions, which are included within the ROBIS tool to help assess specific concerns about potential biases within the review, will be completed and used to help overview authors judge overall risk of bias. We will use the rating guidance published with the ROBIS tool in answering all signalling questions (Whiting 2015). We will judge the risk of bias of each review to be at low, high or unclear risk of bias. We will resolve any disagreements between independent overview authors through discussion, involving a third reviewer if necessary.

If any overview authors are authors on an included review, they will not be involved in the assessment of methodological quality of that review, and this will be done independently by two other overview authors.

The agreed responses to all ROBIS phases and judgement will be tabulated and fully reported within the overview.

### Quality of evidence in included reviews

We will not reassess the quality of individual studies included within reviews but will report the quality of individual studies according to the review authors' assessment.

We will assess the quality of the evidence synthesised within each relevant comparison (i.e. all relevant meta-analyses from included reviews which pool data for one of our pre-stated primary or secondary outcomes of interest) using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach (Guyatt 2008; Guyatt 2011a), which includes the following:

- Risk of bias due to flawed design or conduct of studies (Guyatt 2011b).
- Imprecision (e.g. when confidence intervals for treatment effect are wide) (Guyatt 2011d).
- Inconsistency (e.g. when point estimates vary widely,  $I^2$  is large) (Guyatt 2011e).
- Indirectness (e.g. variations in participants, interventions, comparisons and outcomes) (Guyatt 2011f).
- Publication bias (may be explored with the use of funnel plots and classed as 'not suspected', 'suspected', 'strongly suspected' or 'very strongly suspected') (Guyatt 2011c).

The GRADE approach provides a system for rating quality of evidence and strength of recommendations that is explicit, comprehensive, transparent, and pragmatic and is increasingly being adopted by organisations worldwide. However, difficulties associated with the subjectivity involved in judging grade of evidence has previously been reported, and poor agreement has been found on grading strength of evidence within systematic reviews using GRADE, even amongst experienced systematic reviewers (Berkman 2013). A previous Cochrane overview has reported that it was difficult to achieve agreement between independent overview authors for GRADE judgements when a large number of comparisons needed to be assessed (Pollock 2014), and proposed the use of an objective algorithm to enable transparent, reproducible assignment of GRADE levels of evidence (Pollock 2014; Pollock 2015).

The overview author team will therefore explore use of the iterative methods reported by Pollock 2015 to develop a set of objective criteria for exploring the quality of the specific body of evidence included within this overview. A consecutive sample of five reviews will be used to explore and develop a final algorithm, involving comparison of the subjective grading of evidence applied by three independent overview authors, with data generated using a draft algorithm. The draft algorithm will involve systematic assessment of:

- the number of participants within the analysis;
- the risk of bias of trials contributing participants to the analysis, as reported by the review authors within 'Risk of bias' tables;
- heterogeneity within the analysis, as determined by  $I^2$ ; and



- the methodological quality of the review, as determined by our ROBIS assessment.

However the iterative, exploratory process used to develop the final algorithm may lead to the addition or removal of criteria (using the methods described by [Pollock 2015](#)). We will document this process and detail the final objective algorithm. We will be guided by key publications relating to application of the GRADE framework ([Guyatt 2011a](#)).

Following agreement of the final algorithm, two overview authors will work together to ensure consensus and consistency of entry of objective data pertaining to these criteria onto a spreadsheet, and will apply the objective algorithm to determine whether evidence arising from each comparison relating to one of our pre-stated outcomes of interest was classed as 'high', 'moderate', 'low' or 'very low' within GRADE, based on the following definitions ([Balslem 2011](#)).

- High quality: We are very confident that the true effect lies close to that of the estimate of the effect.
- Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
- Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

## Data synthesis

As stated above, all data synthesis will be grouped and presented according to the type of UI: 1. stress, 2. urgency, 3. mixed, 4. combined populations, 5. unclear.

We will tabulate a summary of systematic review evidence relating to all conservative interventions for UI, clearly signposting which systematic reviews address which interventions, with summary of details of the population of participants, comparisons, volume and quality of evidence. We will categorise the conservative interventions using the categories described in [How the interventions might work](#) and [Figure 1](#). Where conservative interventions are delivered in combination we will categorise these according to the combined interventions, but clearly highlighting the individual interventions.

For each relevant intervention comparison and for both primary and secondary outcome of interest (see [Data extraction and management](#)) we will produce a 'Summary of results' table (see [Table 1](#)) clearly indicating where there is evidence of an effect of conservative interventions. In addition to this summary we will tabulate - for both primary and secondary outcomes - the number of studies and participants included in the comparison, the mean difference or standardised mean difference (for continuous data), the risk ratio or risk difference (for binary data), 95% confidence

intervals, and the  $I^2$  statistic for heterogeneity. We will clearly highlight where the data indicate statistically significant evidence of benefit, harm or no effect, relating this to the assigned GRADE quality of evidence.

## Exploration of subgroups

The objective of this overview is to systematically synthesise the results of data pooled within reviews relating to conservative interventions for different types of urinary incontinence. As part of this objective we plan to explore existing data relating to different subgroups of women. We do not plan to carry out any statistical subgroup comparisons ourselves. Where the included reviews have carried out subgroup analyses relating to our pre-defined subgroups (listed below), using data from one of our primary outcomes, we will extract and tabulate the results of these analyses. We will report the pooled data for all the subgroups as defined within the included reviews, and the results of the statistical test for subgroup differences.

Where possible we will synthesise data from meta-analyses of our stated primary outcomes which relates to the following pre-defined subgroups:

1. Severity of symptoms (mild/moderate/severe)
2. Pregnancy (pregnancy/no pregnancy, and antenatal/postnatal and mode of delivery)
3. Health-related cause of UI (cancer, neurological diseases, chronic respiratory disease, learning difficulties, dementia)
4. Age (pre-menopausal/post-menopausal)
5. Co-morbidities (i.e. any other conditions)
6. BMI (normal/obese/morbidly obese)
7. Ethnicity
8. Duration of symptoms
9. Place of living (living at home, in care home or in nursing home)
10. Socio-economic status.

In addition, where possible we will synthesise data relating to groups of participants with nocturia, nocturnal enuresis and coital incontinence. Data relating to any of these subgroups will be tabulated, grouped according to intervention.

## Statistical analysis

The main aim of this overview is to provide a summary of evidence relating to the effectiveness of conservative interventions for UI. Descriptive summaries of the data relating to comparisons with the included reviews will be reported.

For our three populations of interest (stress UI, urgency UI, mixed UI), and for our primary outcomes of (1) condition-specific quality of life and (2) symptomatic cure or improvement of UI, we will also:

1. Summarise the available data by creating a visual map of the direct comparisons reported by the individual trials included within

the reviews. These network maps will illustrate the number of trials and number of participants within trials. Network maps will be created using Stata software. The mapping function available allows for weighting and colouring options for both nodes and edges in the map, which reveal important differences in the characteristics of treatments or comparisons (Chaimani 2013; Palmer 2016). For example, the nodes and edges can be weighted according to the number of studies or participants involved in each treatment and comparison respectively. These summaries will illustrate the quantity and quality of evidence for different comparisons, but are not designed to summarise effect sizes for the comparisons.

2. Perform subgroup analyses, for comparisons of intervention versus control, placebo or standard care. Subgroup analyses will only be completed following an exploration of the clinical populations included in the trials in the included reviews. Three overview authors, including a content expert, methods expert and statistician, will discuss the available data and reach consensus on whether any data are suitable for meta-analysis. The authors will consider whether the enrolment criteria to the trials of different interventions, contained within different reviews, are similar in relation to etiological factors, symptom severity, comorbidities and other relevant factors. The outcome of these discussions will be documented and reported to ensure transparency of this decision making. Where the clinical populations of trials included in reviews of different interventions are judged to be similar we will estimate the difference between the subgroups and determine its statistical significance (Higgins 2011a). The difference between the summary effects in any two given subgroups will provide an estimate of the indirect comparison of different interventions (Higgins 2011b). If possible, we will complete the following subgroup analyses, for populations of women with stress UI, urgency UI and mixed UI:

- a) Any conservative intervention versus control, placebo or standard care for condition-specific quality of life, with subgroups de-

finied according to type of intervention. Continuous data (means, standard deviations, number of participants) relating to the effects reported by individual trials and included in relevant reviews will be extracted and entered into a subgroup analysis within Review Manager 5 or Stata, and depicted with forest plots. We will compute standardised mean differences for the different subgroups, pooling data from different condition-specific quality of life measurement scales. We will report the test for subgroup differences using an inverse-variance random-effects model for meta-analysis of continuous outcomes (Deeks 2011).

- b) Any conservative intervention versus control, placebo or standard care for symptomatic cure or improvement of UI, with subgroups defined according to type of intervention. Binary counts data (number of events, number of participants) relating to the events reported by individual trials and included in relevant reviews will be extracted and entered into a subgroup analysis within Review Manager 5 or Stata, and depicted with forest plots. We will compute the relative risk for the different subgroups, and report the test for subgroup differences using the generic inverse-variance random-effects model (Deeks 2011).

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\* Indicates the major publication for the study

## ADDITIONAL TABLES

Table 1. Summary of results

	Important difference	Small difference (may not be important)	Little or no difference
<b>High certainty evidence</b>	INTERVENTIONS (insert list) which improve/decrease/prevents OUTCOME	INTERVENTIONS (insert list) which improves slightly/decreases slightly OUTCOME	INTERVENTIONS (insert list) which results in little or no difference in OUTCOME
<b>Moderate certainty evidence</b>	INTERVENTIONS (insert list) which probably improve/decrease/prevents OUTCOME	INTERVENTIONS (insert list) which probably improves slightly/decreases slightly OUTCOME	INTERVENTIONS (insert list) which probably results in little or no difference in OUTCOME
<b>Low certainty evidence</b>	INTERVENTIONS (insert list) which may improve/decrease/prevents OUTCOME	INTERVENTIONS (insert list) which may improve slightly/decrease slightly OUTCOME	INTERVENTIONS (insert list) which may result in little or no difference in OUTCOME
<b>Very low certainty evidence</b>	It is uncertain whether INTERVENTIONS (insert list) improves/decreases/prevents OUTCOME because the certainty of the evidence is low		
<b>No data or no studies</b>	OUTCOME was not measured or not reported or no studies were found that evaluated the impact of INTERVENTION on OUTCOME		

Draft summary of results table. Separate summary of results tables are planned for each of the stated primary and secondary outcomes of interest to this overview.

(Table adapted from presentation by A Oxman at Cochane Meeting, Athens, May 2015).

## APPENDICES

### Appendix I. Cochrane Database of Systematic Reviews search strategy

*[this strategy will be finalised once this approach has been OKed by CEU]*

The Cochrane Database of Systematic Reviews will be searched from inception to the most recent issue using the following search strategy:

- #1 incontinen\*:ti,ab,kw (Word variations have been searched)
- #2 continen\*:ti,ab,kw (Word variations have been searched)
- #3 MeSH descriptor: [Urinary Bladder, Overactive] explode all trees
- #4 MeSH descriptor: [Urinary Bladder, Neurogenic] explode all trees
- #5 MeSH descriptor: [Urinary Incontinence] explode all trees
- #6 ((bladder or detrusor or vesic\*) near/2 (hyper\* or overactiv\*)) .ti,ab,kw.
- #7 urin\* near/2 (leak\* or freq\* or urge\*) .ti,ab,kw.

#8 ((bladder or detrusor or vesic\*) near/5 (instab\* or stab\* or unstab\* or irritab\* or hyperreflexi\* or dys\*ynerg\* or dyskinesi\* or irritat\*))  
 .ti,ab,kw.  
 #9 (bladder\$ near/2 (neuropath\* or neurogen\* or neurolog\*)) .ti,ab,kw.  
 #10 (pollakisur\* or pollakiur\*) .ti,ab,kw.  
 #11 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10

## CONTRIBUTIONS OF AUTHORS

Doreen McClurg - Contribute to methodological decisions, and provide content expertise. Assess reviews for inclusion. Act as 3rd reviewer for disagreements during data extraction, and quality assessment. Contribute to decision making over assessment of quality of evidence within reviews. Write discussion and conclusion. Read and comment on all drafts of overview.

Alex Pollock - Write protocol. Contribute to methodological decisions. Act as 3rd reviewer for disagreements during data extraction, and quality assessment. Contribute to decision making over assessment of quality of evidence within reviews. Data synthesis. Write methods and results.

Pauline Campbell - Contribute to methodological decisions. Run searches, manage search results. Assess quality of reviews using ROBIS and quality of evidence within reviews using agreed approach to GRADE. Contribute to writing of methods and results.

Christine Hazelton - Data extraction and management. Assess quality of reviews using ROBIS and quality of evidence within reviews using agreed approach to GRADE. Data entry. Contribute to writing of results.

Andrew Elders - Lead discussion and decision relating to completion of statistical analysis. Provide advice relating to extraction of meta-analysis data. Carry out statistical analysis. Read and comment on all drafts of overview.

Suzanne Hagen - Contribute to methodological and statistical decisions, and provide content expertise. Assess reviews for inclusion. Act as 3rd reviewer for disagreements during data extraction, and quality assessment. Contribute to decision making over assessment of quality of evidence within reviews. Read and comment of all drafts of overview.

## DECLARATIONS OF INTEREST

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